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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,812

12/14/2004

Harald Breivik

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09/27/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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EXAMINER

CARR, DEBORAH D

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

09/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,812	Applicant(s) BREIVIK ET AL.	
	Examiner Deborah D. Carr	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-58 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 32-58 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/04, 1/07, 3/07</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 32-58 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims as currently amended refer to a pharmaceutical composition containing EPA/DHA ethyl esters in a pharmaceutically to therapeutically treat hypertriglycerdaemia. There is no written disclosure that discloses what the “pharmaceutically effective concentration” to therapeutically effective amount treat hypertriglycerdaemia. Page 15 of the specification refers to a pharmaceutical composition that can be used to treat hypertriglycerdaemia but no disclosure about treatment dosages.

Also it should be noted that the amounts given for various pollutants such as PCDD, PCDF, & TE_PCB is not disclosed in the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 32-35, 38-39, 42-46 rejected under 35 U.S.C. 102(b) as being clearly anticipated by EPAX Product Specifications for EPAX 4020EE or 5500EE or 6000EE or 6010EE.

All four EPAX products listed supra are marine oils containing both eicosapentaenoi acid ethyl ester and docosahexaenoi acid ethyl ester in a pharmaceutically effective concentration to therapeutically treat hypertriglycerdaemia wherein the amount of pollutants such as BDE 47, PCDDs, PCDDs, and TE-PCBs are less than the instant recited limits.

5. Claims 47-50, 53-56 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dam et al.

Dam et al. teaches n-3 fatty acids namely eicosapentaenoi acid ethyl ester and docosahexaenoi acid ethyl ester contained in Omacor™ (see attached product specification) in a pharmaceutically effective concentration to therapeutically can treat hypertriglycerdaemia.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 36-37, 40-41, 51-52, 57-58 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 36, 40, 51, 57

Claims 36, 40, 51, 57 contain the word “about” in reference to the acid value parameter. The specification indicates on page 33, lines 4-5, 31 and page 34, lines 5-6 an acid value of “about 0.2 mg KOH/g” is read to mean an of 0.1 - 0.2 mg KOH/g. When using the term “about” is understood exactitude is not claimed but a contemplated variation; thus, “an acid value of “about 0.2 mg KOH/g” in claims 36, 40, 51, 57 describes limitations from a chemically operative lower limit to an upper limit beyond 1-2.

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Therefore this claim reads on an acid value of more than or less than 0.1 - 0.2 mg KOH/g, which is not described in the specification.

Claims 37, 41, 52, 58

Claims 37, 41, 52, 58 read on an acid value range between 0.2 - 0.3 mg KOH/g which is not described in the specification. As explained supra, the only description given of the acid value falls within the range of 0.1 - 0.2 mg KOH/g. The range contained in these claims is considered to be new matter.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 58 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 58 is rendered indefinite by the phrase "is less is between in line 2 of the claim.

Clarification is required.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah D. Carr whose telephone number is 571-272-0637.

The examiner can normally be reached on Monday-Friday 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


DEBORAH D. CARR
PRIMARY EXAMINER

ddc